

**COMAR 10.24.15**  
**STATE HEALTH PLAN FOR FACILITIES AND SERVICES:**  
**SPECIALIZED HEALTH CARE SERVICES**

**ORGAN TRANSPLANT SERVICES:**  
**REGULATORY ISSUES AND POLICY OPTIONS**

**ANALYSIS OF PUBLIC COMMENTS**  
**AND STAFF RECOMMENDATIONS**

**NOVEMBER 15, 2001**



# Organ Transplant Services: Regulatory Issues and Policy Options

## Summary and Analysis of Public Comments Received on the Options Paper and Staff Recommendations

### I. Introduction

During 2001-2002, the Maryland Health Care Commission will update the State Health Plan for organ transplant services (COMAR 10.24.15). This chapter of the State Health Plan for Facilities and Services (SHP) has included policies, standards, and need projections for organ transplant services since January 1999.

To provide an opportunity for the public to participate in the process of updating the plan prior to the formal promulgation of regulations, the Commission staff prepared an options paper, *Organ Transplant Services: Regulatory Issues and Policy Options*. This paper provided background information on organ transplant services in Maryland, identified key issues in planning and regulating organ transplant services, and examined the impact of a number of policy options.

The Commission released the options paper on September 13, 2001, and invited interested organizations and individuals to submit written comments until October 9, 2001. The first step in a comprehensive review of this SHP chapter, the paper provided an opportunity for interested parties to raise issues and suggest policy options for the Commission's consideration.

This document provides a summary and analysis of the written comments received on the options paper. The Commission's staff will use the public comments in preparing a draft of the updated SHP chapter. This draft plan will be presented at the Commission's meeting on November 15, 2001, when the Commission will release the staff draft for public comment. After considering written comments on the draft SHP chapter, the Commission will initiate the formal process by which administrative regulations are adopted or amended, which requires an opportunity for public comment on any proposed changes to regulations.

## II. Public Comments and Staff Recommendations

Three organizations submitted written comments:

1. Johns Hopkins Health System (JHHS) – Ronald R. Peterson, President
2. MedStar Health (MedStar) – John L. Green, Executive Vice President, Corporate Services
3. University of Maryland Medical Center (UMMC) – Stephen C. Schimpff, M.D., Chief Executive Officer

A complete set of the written comments may be obtained by contacting the Maryland Health Care Commission, Health Resources Division, at 410-764-3232.

### ***A. Categories of Covered Transplant Programs***

*Option 1: Current Categories of Transplant Programs*

*Option 2: Additional Categories of Transplant Programs*

#### **◆ Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 1.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1.

#### **◆ Changes Suggested by Comments:**

No changes were suggested by the comments. The three organizations submitting public comments all supported Option 1, maintaining the current categories of covered transplant programs.

#### **◆ Staff Analysis:**

The current policy of transplants covered by the State Health Plan (SHP) is consistent with the definitions of the United Network for Organ Sharing (UNOS) and the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT). The categories of covered programs are solid organs, including kidney, liver, pancreas, heart, lung, heart-lung, intestine; hematopoietic stem cells, including autologous and allogeneic bone marrow; and other transplantable cells, including islet cells and hepatocytes. In addition, the Commission may determine other organs and cell types, as needed.

#### **◆ Staff Recommendation:**

Staff recommends maintaining the current SHP policy on categories of transplant programs covered by the Certificate of Need (CON) Program.

## **B. Need Projection Policies**

### **1. Definition of Planning Regions**

*Option 1: Regional Service Areas Consistent with OPO Regions*  
*Option 2: Regional Service Areas Excluding Out-of-State Areas*

#### **◆ Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 2. Further, Hopkins proposed that “the Commission recommend the merger of the organ procurement service areas for Washington, D.C. and Maryland, which would then eliminate the geographic disequilibrium and potentially allow more Maryland transplant patients to benefit from Maryland donors.” JHHS suggested that the “Commission can support implementation of this policy change by adopting a definition of planning regions that excludes out-of-state components and by making a specific suggestion of that change to UNOS and CMS.”

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of a modified version of Option 2 that would merge the Maryland and Washington Organ Procurement Organizations (OPOs). UMMC believes that “consolidation of the two OPOs serving this region would be advantageous from the perspective that organs procured in Montgomery, Prince George’s, and Charles counties should be directed towards Maryland patients who are waiting for the ‘gift of life.’ A merger of these two entities would also create efficiencies that would lower the cost of transplantation for Marylanders and those residing in the Washington DC metropolitan area.”

#### **◆ Changes Suggested by Comments:**

Two organizations wrote in support of changing the regional planning areas. Both organizations also recommended the merger of the two OPOs in the region, the Transplant Resource Center of Maryland (TRC) and the Washington Regional Transplant Consortium (WRTC). The rationale of both organizations for merging the OPOs is to increase the fairness of organ distribution to “Maryland patients.” JHHS suggested the adoption of Option 2 in the interim, while UMMC suggested a modification to Option 2 resulting in one large planning region, including all service areas of the two OPOs.

#### **◆ Staff Analysis:**

Due to the explicit relationship between utilization of transplant services and the limited supply of organs, planning regions must be considered with respect to existing organ procurement and allocation policies, that is, planning regions need to be inherently linked with OPOs.

Three types of rules govern organ allocation in the United States:

1. Federal statutory requirements set forth in the National Organ Transplant Act (NOTA), passed on October 19, 1984, and amended in 1988 and 1990. NOTA established the framework for a system of effective procurement and equitable allocation of human organs for transplant throughout the country and provided for federal reimbursement of transplant service costs.
2. Federal regulations promulgated by the Centers for Medicare and Medicaid Services (CMS), formerly HCFA, to implement the statute.
3. Policies of the United Network for Organ Sharing (UNOS), the contractor hired to operate the organ allocation structure mandated by Congress.

NOTA requires a national system for distribution of organs, and the policies of the Organ Procurement and Transplantation Network (OPTN) currently require organ sharing across State lines. However, some States, among them Arkansas, Florida, Louisiana, Mississippi, Oklahoma, South Carolina and Tennessee<sup>1</sup>, have passed laws that limit organ sharing, requiring that the OPO first attempt to match the organ with an eligible transplant candidate within the State, regardless of status. That is, they give preference in organ allocation to state residents whenever a state resident is not the next designee on the national list. Such laws would almost certainly jeopardize the compliance of transplant hospitals and OPOs within that State with rules and requirements of the OPTN, and thus would put at risk their ability to obtain Medicare and Medicaid reimbursement.

CMS defines the geographic procurement territory for OPOs, within which they concentrate their procurement efforts. Service areas are defined to ensure that a geographical area is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs. Service areas are mapped by county borders and are re-assigned by CMS on a routine basis. From the year 2000, service areas are open for competition every 4 years; during this time any OPO can request more or less service. Prior to the year 2000, these designations lasted for a period of 2 years. CMS negotiates with the OPOs to reach the final assignment. An OPO service area is required to include a population of at least 2.5 million or contain at least fifty potential donors a year, unless the service area comprises an entire state.

As of August 13, 2001, there were 59 operating OPOs in the United States:

- 36 OPO service areas – cross no State borders;
- 10 OPO service areas – cover 2 States, or parts thereof;
- 10 OPO service areas – cover 3 States, or parts thereof;
- 2 OPO service areas – cover 4 States, or parts thereof; and
- 1 OPO service area – covers 7 States, or parts thereof.

CMS policies include provisions to modify these areas. If an OPO wishes to change its service area or merge, it must submit new certification forms. In addition, two or more OPOs may enter into a sharing arrangement, that is, an arrangement to share organs, interregionally or

---

<sup>1</sup> See ARK. CODE ANN. § 20-17-617 (Michie 1997); FLA. STAT. ch. 732.922 (1998); LA. REV. STAT. ANN. § 17:2353 (West 1998); MISS. CODE ANN. § 41-39-15 (1998); OKLA. STAT. tit. 63, § 2204 (1998); S.C. CODE ANN. § 44-43-410 (Law. Co-op. 1998); S.B. 311, 101st G.A. (Tenn. 1999).

intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement with the prior approval by the UNOS Board of Directors. Organs must be distributed within the sharing area on the basis of a common Patient Waiting List.

Currently there is a moratorium on the current recertification process for OPOs due to the “Organ Procurement Organization Certification Act of 2000.” The purpose of the law is to revise the performance standards and certification process for organ procurement organizations. Recertification for OPOs cannot occur until new rules are promulgated, due not later than January 1, 2002. The Commission will take into consideration federal actions related to modifications made in the OPO recertification process and regions during the next update of the plan.

The fairness of organ distribution to patients receiving transplants in Maryland programs has been raised as an issue. In effect, the concern is due to the policies of UNOS concerning the allocation of organs for transplantation. These policies, among other considerations, determine the geographic sequence in which organs are offered to patients on the waiting list. Simplifying a complex distribution system, cadaveric kidneys and livers are allocated initially to local patients within the OPO service area, then regionally, and finally nationally if they cannot be allocated locally. Thoracic organs (hearts and lungs) are allocated locally, then within Zone A (a concentric circle of 500 nautical miles with the donor hospital at the center) and finally to Zone B (a concentric circle of 1,000 nautical miles with the donor hospital at the center). TRC and WRTC are both located within Region 2, along with OPOs covering Delaware, New Jersey, Pennsylvania, and West Virginia.

This process, as noted by UMMC and JHHS, results in organs procured from the three Maryland counties within the Washington region being allocated with priority to patients on the waiting list within the Washington region, which consists of Washington, D.C. and Northern Virginia as well. As Table 1 shows, distribution of solid organs is primarily within the local service areas of the OPOs; this occurs due to the distribution policies giving preference to providing organs to patients on the local waiting list. For the TRC this ranges from 61 percent to 100 percent being transplanted locally, while for WRTC the range is from 57 percent to 83 percent.

**Table 1: Number of Organs Recovered and Transplanted: Maryland and Washington Regions, 2000**

<b>Organ</b>	<b>Total Organs Recovered</b>	<b>Total Organs Transplanted</b>	<b>No. of Organs Transplanted Locally</b>	<b>No. of Organs Transplanted Outside Local Area</b>	<b>Recovery Rate per 100,000 Pop</b>	<b>Locally Transplanted per 100,000 Pop</b>
<b>Maryland Region (TRC)</b>						
Kidney	161	135	82	53	4.82	2.45
Pancreas	28	26	26	0	0.84	0.78
Liver	51	43	38	5	1.53	1.14
Lung	26	26	26	0	0.78	0.78
Heart	26	25	17	8	0.78	0.51
<b>Washington Region (WRTC)</b>						
Kidney	152	119	75	44	3.63	1.79
Pancreas	27	18	15	3	0.64	0.36
Liver	64	56	39	17	1.53	0.93
Lung	33	32	20	12	0.79	0.48
Heart	32	30	17	13	0.76	0.41

Source: [www.ustransplant.org](http://www.ustransplant.org), accessed October 11, 2001. Based on data available as 06/01/2001.

Note: Rate of recovery and local transplants involve no adjustments for the death rate of the local population, or the length of the waiting lists in the local area.

The merger of the two OPOs may result in cost efficiencies as noted by UMMC; however, the general issue raised by the two organizations appears to be related to access to the limited supply of organs. As noted, again by UMMC, “the geographic designation of regions by the CMS are more relevant than state borders.” Moreover, the State Health Plan acknowledges the importance of out-of-state services to assure reasonable geographic access for a portion of Maryland’s population (Principle 4). Due to the specialized nature of organ procurement and transplantation, it would not be appropriate to exclude out-of-state areas.

It should also be noted that Maryland residents in Charles, Montgomery and Prince George’s counties use hospital inpatient services within the District of Columbia on a regular basis, not just for organ transplantation. In 1999 (most recent data for DC hospitals), there was an 8 percent out-migration of all Maryland residents for basic inpatient hospital services<sup>2</sup> to DC hospitals, while 25 percent of discharges for residents living in Charles, Montgomery and Prince George’s counties were in DC hospitals (Table 2).

<sup>2</sup> Basic hospital services were defined as non-tertiary care. For the purpose of this report, the definition of tertiary care was based on the magnitude of resource intensity required for a Diagnosis Related Group (DRG). Relative weights are values assigned to each DRG that identify its relative weight in terms of resource use compared to a standardized value. In this report, a DRG having a weight of less than 4.0 was defined as non-tertiary or basic inpatient services; this results in the exclusion of DRGs such as organ transplants, craniotomy procedures for multiple significant trauma, coronary bypass with PTCA, some rehabilitation services, severe burns, and low birth weight newborns.

**Table 2: Out-migration of Maryland Residents to Hospitals in Washington, D.C. for Basic Inpatient Services: 1999**

Location of Hospital	Discharges for Basic Inpatient Services	
	All Maryland Residents	Maryland Residents in Charles, Montgomery and Prince George's Counties
Maryland	553,249	127,166
District of Columbia	49,020	43,030
Out-Migration	8.1%	25.3%

Source: MD Discharge Abstract Data, 1999, and DC hospitals discharge data, 1999.

Note: Discharges from all Maryland and DC hospitals for DRGs with a relative weight of less than 4.0.

◆ **Staff Recommendation:**

Staff recommends the continued use of OPO-designated service areas as regional service areas for planning organ transplant services. There are appropriate federal procedures for OPOs to address service area designations and organ allocation issues.

## 2. Patient Migration Patterns

*Option 1: Constant Patient Migration Patterns Between Base and Target Years*

*Option 2: Changes in Migration Patterns Between Base and Target Years for the State of Maryland*

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 2, allowing for an adjustment to the in- and out-migration patterns.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 2. MedStar rejects the constant migration patterns that Option 1 would include in need methodologies as unrealistic, and favors the inclusion of a factor in the methodology that accounts for in- and out- migration for each designated planning region.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – described Option 2 as the preferred methodology. In general, UMMC believes that migration in and out of Maryland should be a determinant of future need for health care services, especially highly specialized services such as organ transplants. UMMC expressed the view that “the ability to adjust retention rates based on trends in actual experience is preferable to holding rates constant between the base and target year.”

◆ **Changes Suggested by Comments:**

All three organizations suggested that Option 2 was preferred to allow for the adjustment of retention rates.



◆ **Staff Analysis:**

Currently, the migration pattern is determined by the average in- and out-migration over the most recent three years for each organ type. The migration rates were determined by summing the number of transplant cases experienced over the past 3 years for each organ type in each region. Out-migration is then calculated by dividing the number of local residents going outside their region by the total regional resident cases. In-migration is calculated by dividing the number of nonresidents seeking care within a region by the total regional facility cases. The calculated migration rates are kept constant for the three-year planning horizon. There is an interest in applying a retention rate factor as part of the need projection methodology. Tables 3 and 4 show the historical three-year migration rates and numbers of transplants, and the migration rate used in projecting need for 2003 for each organ type for the Maryland region and Washington region, respectively.

**Table 3: In-Migration and Out-Migration from the Maryland Region (based on OPO Planning Regions)**

Year	Kidney		Pancreas		Liver		Heart		Lung	
	%	n	%	n	%	n	%	n	%	n
<b>In-Migration</b>										
1998	43.3	176	64.9	48	36.3	29	40.0	10	59.3	16
1999	37.0	187	65.6	63	52.6	40	33.3	9	54.5	18
2000	36.9	220	48.7	37	37.5	30	42.9	9	56.0	14
Rate used for 2003	38.7	362	60.2	55	42.0	35	38.4	8	56.5	28
<b>Out-Migration</b>										
1998	7.7	29	13.2	7	17.5	17	29.4	10	20.0	4
1999	4.8	22	-	-	13.3	10	18.8	6	13.0	3
2000	4.5	24	-	-	19.2	20	23.8	5	7.4	2
Rate used for 2003	7.5	51	6.8	3	25.5	16	31.8	4	19.6	3

Source: UNOS, data as of July 13, 2001.

**Table 4: In-Migration and Out-Migration from the Washington Region (based on OPO Planning Regions)**

Year	Kidney		Pancreas		Liver		Heart		Lung	
	%	n	%	n	%	n	%	n	%	n
<b>In-Migration</b>										
1998	20.6	50	37.0	10	36.4	16	30.8	8	30.0	3
1999	19.1	53	33.3	5	40.4	23	26.1	6	46.2	6
2000	18.8	48	26.7	4	26.8	15	25.0	4	42.1	8
Rate used for 2003	19.4	76	33.3	5	34.4	19	27.7	4	40.5	13
<b>Out-Migration</b>										
1998	15.0	34	37.0	10	56.9	37	5.3	1	46.2	6
1999	15.1	40	60.0	15	47.7	31	22.7	5	53.3	8
2000	16.1	40	38.9	7	40.6	28	45.5	10	54.2	13
Rate used for 2003	15.4	42	45.7	6	48.2	34	25.4	7	51.9	25

Source: UNOS, data as of July 13, 2001.

In a few situations, it may be appropriate to adjust retention rates, for example, when a Certificate of Need is awarded in an area where no program existed, or after closure of a program in an area where no other program exists.

Analysis of the in- and out-migration for the Maryland and Washington regions over the past three years shows often there are small volumes and irregular patterns. These factors make it difficult to project retention rates reliably.

A short planning horizon (e.g., three years), however, would allow recent changes in the environment to be reflected in the utilization data and hence be reflected in the updated projections.

◆ **Staff Recommendation:**

Staff recommends maintaining the current policy on keeping migration rates constant, along with a short planning horizon. (See Appendix B for in- and out-migration rates used in projections.)

### **3. Use Rate Assumptions in Projecting Future Cases**

*Option 1: Standard Increase Across Transplant Types for All Ages*  
*Option 2: Most Recent Three Years of Data to Calculate Average Change for Each Transplant Program*  
*Option 3: Constant Base Year Regional Use Rates*  
*Option 4: Need Projections for Two Age Groups*

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 4, with the belief that it “will be a more precise method for projecting future cases.”

**John L. Green, Executive Vice President of Medstar Health** – believes that a weakness of the current methodology is its application of a general use rate to all programs or categories of programs. MedStar suggested the application of use rate assumptions at the program level as the most appropriate method of deriving need. MedStar stated that either Option 2 or Option 3 is preferable to Option 1.

Medstar also expressed concern that the use rates are based on the number of cases performed in a region per 100,000 population of that region (that is, capturing in-migration), which could inflate regional use rate. This was raised after noting the significantly different use rates between the two planning regions.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** - wrote in support of a combination of Option 2 and Option 4, that is, using the most recent three years of data to calculate the average change for each transplant program and providing need projections based on age-specific use rates.

#### ◆ **Changes Suggested by Comments:**

Under this policy, it was possible to suggest two options, one regarding the method of projecting use rates, and another addressing projections for two different age groups.

In regard to the method of projecting use rates, MedStar preferred either Option 2 or 3, to Option 1; and UMMC supported Option 2.

JHHS and UMMC supported Option 4 to provide need projections for age-specific use rates, both recommending the definition of pediatric as aged less than 18 years, with adults being 18 years and older, consistent with UNOS groupings.

MedStar felt that the method of calculating the use rates needed to be reviewed, based on a concern that “the use rates are based on the number of cases performed in a region per 100,000 population of that region, *but include transplants performed on patients who reside outside the region.*”

#### ◆ **Staff Analysis:**

MedStar noted the significantly different use rates between the two planning regions and expressed concern that this may be due to rate calculation methodology. MedStar questioned whether the use rates are based on the number of cases performed in a region per 100,000 population of that region (that is, capturing in-migration). In fact, the number of cases used to calculate the use rate for each region is based on the total number of transplants performed in any region on residents of that region. Calculation of the projected number of cases for each type of organ transplant in each region then takes into consideration the historical in- and out-migration rates. The completeness of the UNOS database allows a relatively accurate calculation of use rates for solid organ transplants. However, bone marrow transplant use rates, as noted in the options paper, are not as accurate due to the assumption that the out-migration of Maryland residents is to the District of Columbia or Northern Virginia. Data on out-migration to other areas are not routinely available.

Use rate assumptions, migration patterns, and consequent projections are reliant on a number of data sources.

- UNOS provides up-to-date complete data on all solid organ transplants across the United States, providing data on patient county, region of care and age group.
- The Maryland Discharge Abstract Data provides up-to-date data for all Maryland hospitals. The data elements include length of stay, charges, payer, transplant type (including bone marrow transplants), and hospital.
- Discharge data is also collected from DC hospitals to identify discharges of Maryland and Washington region residents obtaining care from hospitals in the District of Columbia. This data often lags behind by one year before it becomes available to the MHCC.
- The Health Systems Agency of Northern Virginia provides data from Northern Virginia hospitals.
- The MHCC conducts a survey of hospitals providing bone marrow transplants. Data collected includes type of bone marrow transplant and age group. In addition, where possible, patient cases (all ages, all transplant types) are identified as to area of residence.

- Population data are obtained from the US Census Bureau and other sources, often limited in regard to estimated historical data and projected data.

**Table 5: Number of Transplants performed by Patient Region of Residence and Location of Transplant Center: All Ages, 2000**

Organ	Patient Region	Region of Care			Total
		Washington	Maryland	Other	
Kidney	Maryland	18	376	6	400
	Washington	208	31	9	248
	Other	30	189	13,376	13,595
	<b>Total</b>	<b>256</b>	<b>596</b>	<b>13,391</b>	<b>14,243</b>
Pancreas	Maryland	0	39	0	39
	Washington	11	5	2	18
	Other	4	32	1,250	1,286
	<b>Total</b>	<b>15</b>	<b>76</b>	<b>1,252</b>	<b>1,343</b>
Liver	Maryland	6	50	14	70
	Washington	41	10	18	69
	Other	9	20	4,786	4,815
	<b>Total</b>	<b>56</b>	<b>80</b>	<b>4,818</b>	<b>4,954</b>
Heart	Maryland	3	12	2	17
	Washington	12	4	6	22
	Other	1	5	2,148	2,154
	<b>Total</b>	<b>16</b>	<b>21</b>	<b>2,156</b>	<b>2,193</b>
Lung	Maryland	2	11	0	13
	Washington	11	6	7	24
	Other	6	8	905	919
	<b>Total</b>	<b>19</b>	<b>25</b>	<b>912</b>	<b>956</b>

Source: UNOS data as of July 13, 2001. Excludes all federal data.

Further concern expressed by MedStar was regarding the population base used for calculating use rates. As noted, the Washington region includes some counties of Maryland, Washington, D.C. and Northern Virginia. Table 6 shows the localities included in each region and their respective population data.

Based on the data in Tables 5 and 6, the use rates were calculated, as shown in Table 7.

**Table 6: Resident Population Data for Washington and Maryland Regions: All Ages, 2000**

Maryland Region		Washington Region	
Localities	Population	Localities	Population
Allegany County	65,122	District of Columbia	572,059
Anne Arundel County	467,778	Prince George's County, MD	772,981
Baltimore City	602,981	Montgomery County, MD	850,424
Baltimore County	711,308	Charles County, MD	121,558
Calvert County	76,575	Arlington, VA	189,453
Caroline County	29,310	Fairfax, VA	969,749
Carroll County	151,628	Fauquier, VA	55,139
Cecil County	83,041	Loudoun, VA	169,599
Dorchester County	28,746	Prince William, VA	280,813
Frederick County	189,500	Alexandria City, VA	128,283
Garrett County	28,603	Fairfax City, VA	21,498
Harford County	221,028	Falls Church City, VA	10,377
Howard County	246,668	Manassas City, VA	35,135
Kent County	18,188	Manassas Park City, VA	10,290
Queen Anne's County	40,987		
Somerset County	19,451		
St. Mary's County	89,050		
Talbot County	32,942		
Washington County	118,563		
Wicomico County	76,721		
Worcester County	43,313		
<b>Maryland Region Total</b>	<b>3,341,503</b>	<b>Washington Region Total</b>	<b>4,187,358</b>

Source: MD – Data June 1999 MD Dept. of Planning, with Feb. 2000 update; DC – 2000 Census; VA – 2000 Census.

**Table 7: Projected Use Rates by Patient Residence: All Ages, 2003**

	Organ Type									
	Kidney		Pancreas		Liver		Heart		Lung	
Pt Region	MD	DC	MD	DC	MD	DC	MD	DC	MD	DC
Projected Use Rate	11.97	5.92	1.17	0.43	2.09	1.65	0.51	0.53	0.39	0.57

Utilization data related to federal programs were excluded in all calculations in determining the use rate and projecting need. The State Health Plan establishes policies for programs covered by the Certificate of Need Program. Only non-federal programs are CON-regulated. Additionally, federal transplant programs are designated by federal agencies as specialized services for specific groups that may not usually reside in an area.

A comparison of the projected use rates and cases with actual experience is provided in Tables 8 and 9. The methodology resulted in two of the five solid organ transplant need projections being over- or under- estimated by greater than 45 percent for the Maryland region. The Washington region was projected with two out of three transplants being under- or over- estimated by more than 40 percent.

**Table 8: Comparison of Projected and Actual 2000 Use Rates for Solid Organ Transplants**

Transplant Program	Measure	Patient Residence			
		Maryland Region		Washington Region	
		<i>Projected</i>	<i>Actual</i>	<i>Projected</i>	<i>Actual</i>
<b>Kidney</b>	Use Rates per 100,000 Population	8.27	11.97	5.48	5.92
	Difference between Projected and Actual Use Rates	45%		8%	
	Number of Cases	277	400	222	248
	Difference between Projected and Actual Cases	44%		12%	
<b>Pancreas</b>	Use Rates per 100,000 Population	1.41	1.17	0.67	0.43
	Difference between Projected and Actual Use Rates	-17%		-36%	
	Number of Cases	47	39	27	18
	Difference between Projected and Actual Cases	-17%		-33%	
<b>Liver</b>	Use Rates per 100,000 Population	1.82	2.09	1.78	1.65
	Difference between Projected and Actual Use Rates	15%		-7%	
	Number of Cases	61	70	72	69
	Difference between Projected and Actual Cases	15%		-4%	
<b>Heart</b>	Use Rates per 100,000 Population	1.06	0.51	0.88	0.53
	Difference between Projected and Actual Use Rates	-52%		-40%	
	Number of Cases	36	17	36	22
	Difference between Projected and Actual Cases	-53%		-39%	
<b>Lung</b>	Use Rates per 100,000 Population	0.39	0.39	0.24	0.57
	Difference between Projected and Actual Use Rates	0%		139%	
	Number of Cases	13	13	10	24
	Difference between Projected and Actual Cases	0%		140%	

Sources: Projected data: COMAR 10.24.15, February 2000. Actual data: UNOS, as of July 13, 2001. Population data: MD – Data June 1999 MD Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

The need projections for autologous bone marrow transplants in the Maryland region were underestimated by approximately 12 percent, while allogeneic bone marrow transplants were overestimated by approximately 30 percent. For the Washington region, the projected use rates were underestimated by 45 percent for both autologous and allogeneic bone marrow transplantation.

**Table 9: Comparison of Projected and Actual 1999 Use Rates for Hematopoietic Stem Cell Transplants**

Transplant Program	Measure	Patient Residence			
		Maryland Region		Washington Region	
		<i>Projected</i>	<i>Actual</i>	<i>Projected</i>	<i>Actual</i>
<b>Autologous Bone Marrow</b>	Use Rates per 100,000 Population	5.60	4.90	4.50	2.49
	Difference between Projected and Actual Use Rates	-12%		-45%	
	Number of Cases	188	163	182	101
	Difference between Projected and Actual Cases	-13%		-45%	
<b>Allogeneic Bone Marrow</b>	Use Rates per 100,000 Population	1.33	1.74	1.47	0.81
	Difference between Projected and Actual Use Rates	31%		-45%	
	Number of Cases	45	58	60	33
	Difference between Projected and Actual Cases	29%		-45%	

Sources: Projected data: COMAR 10.24.15, February 2000. Actual data: Maryland Discharge Abstract, DC Discharge Data, HSANV as of July 2001. Population data: MD – Data June 1999 MD Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

In a health care service such as organ transplantation, with the limiting factor not so much on transplant center capacity but on organ supply, it is difficult to anticipate future utilization. Although calculating use rates by age-specific groups would more closely reflect the different usage patterns for pediatric and adult populations, with such low volumes it is particularly difficult to calculate average change for each transplant program over the most recent three-year period (Table 10).

**Table 10: Number of Pediatric Transplants (Persons under 18 years of age): Maryland and Washington Region Transplant Centers, 1998-2000**

Organ Type	Region of Care					
	1998		1999		2000	
	MD	DC	MD	DC	MD	DC
Heart	0	0	0	3	2	2
Kidney	15	14	11	16	7	7
Liver	18	0	11	0	13	0
Lung	1	0	1	1	0	0
Pancreas	1	0	0	0	0	0

Currently, the Children's National Medical Center is the only facility in the Maryland and Washington regions providing pediatric-only transplant services. Johns Hopkins Hospital, University of Maryland Medical Center and Georgetown University Medical Center provide services to the pediatric and adult populations. Programs providing pediatric care must have specialized facilities, equipment, and personnel for this population.

◆ **Staff Recommendation:**

Staff recommends the changing of the current methodology to project need based on the trend of utilization from the most recent three-year period for each program (Option 2). Need projections should continue to be calculated for the population as a whole. (See Appendix B for projected use rates and cases.)

#### 4. Length of Planning Horizon

<i>Option 1: Three-Year Planning Horizon</i> <i>Option 2: Five-Year Planning Horizon</i>
---

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 2, stating that it provides greater stability with respect to implementing recommendations included in the State Health Plan.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1, as it was consistent with other specialized health care services.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 2, stating that it provides greater stability with respect to implementing recommendations included in the State Health Plan.

◆ **Changes Suggested by Comments:**

Two organizations suggested lengthening the planning horizon to five years, while the third organization suggested keeping the current three-year planning horizon.

◆ **Staff Analysis:**

From the above discussion, projecting future utilization of a service that is low-volume and dependent on an organ supply influenced by many factors is difficult. Projections that cover longer periods of time tend to be less reliable.

A shorter planning horizon provides the ability to incorporate actual changes in use rates and represent emerging trends, including changes in migration patterns.

◆ **Staff Recommendation:**

Staff recommends maintaining the current planning horizon of three years.



## 5. Determination of the Need for a New Program

<i>Option 1: Current Methodology</i> <i>Option 2: Revised Methodology</i>
--

### ◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 1.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1.

### ◆ **Changes Suggested by Comments:**

The three organizations submitting public comments all supported Option 1, maintaining the current determination of the need for a new program.

### ◆ **Staff Analysis:**

The current methodology to determine need for a new program includes that an application for a new program will be considered only if both of the following criteria are met:

- (1) The difference between the projected transplant cases (3-year planning horizon) and the transplant cases in the current year is greater than the threshold utilization standard; and
- (2) All programs meet the State Health Plan minimum utilization standard in the current year.

This supports the policy that “fewer organ transplant services operating at higher volumes are preferable to more programs at threshold or minimum volumes.”

### ◆ **Staff Recommendation:**

Staff recommends maintaining the current SHP policy on the method of determining the need for a new program.

## **C. Quality of Care Policies**

### **1. Minimum and Threshold Volume Standards**

*Option 1: Current Minimum Volume Standards*  
*Option 2: Revised Minimum and Threshold Volumes*  
*Option 3: Enforcement of Minimum Volume Standards as Condition of CON*  
*Option 4: Certification and Accreditation*

#### **◆ Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 1.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1.

#### **◆ Changes Suggested by Comments:**

The three organizations submitting public comments all supported Option 1, maintaining the current minimum and threshold volume standards.

#### **◆ Staff Analysis:**

The current minimum volume standards, recommended by the Technical Advisory Committee on Organ Transplant Services, are generally consistent with accreditation and reimbursement standards.

#### **◆ Staff Recommendation:**

Staff recommends maintaining the current policy on minimum and threshold volume standards.

## **D. Cost of Care Policies**

### **1. Cost Efficiency Standard**

*Option 1: Revenue-Neutral Agreement*  
*Option 2: Cost Efficiency Preference Standard*

#### **◆ Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 1.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 2, so that policies are “consistent among all of the specialized services and reflect the most recent changes in the HSCRC rate-setting system.”

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1. UMMC felt that “the current pressures from private and public payors on healthcare cost inflation and the HSCRC’s charge per case targets are sufficient incentives to maintain the best balance between program effectiveness and costs to the health care system.”

◆ **Changes Suggested by Comments:**

Two organizations submitting public comments supported Option 1, maintaining a revenue-neutral agreement with the HSCRC. One organization supported the option of introducing a cost efficiency preference standard, in the case of a comparative review.

◆ **Staff Analysis:**

Organ transplants are high-cost procedures. In calendar year 2000, the average charge for a liver transplant at Johns Hopkins was \$181,974 and at the University of Maryland Medical Center it was \$143,322. Other types of organ transplants are also very expensive and ranged from a low of \$23,411 for allogeneic bone marrow transplantation at Sinai Hospital to an average cost of \$208,257 at the University of Maryland Medical System for heart transplantation. Given this high cost, it is very important to judge an applicant’s efficiency in providing organ transplant services. Research has demonstrated the value of high volumes in organ transplant services and this research clearly applies to the number of organ transplants that a hospital is projecting. Programs become more efficient as they perform increasing numbers of transplants. Preference should be given to the hospital whose projected average charge for organ transplant services compares most favorably to the other hospitals in a comparative review and the State of Maryland as a whole.

In evaluating cost efficiency, the Commission should also examine the efficiency of the hospital as a whole and the effect that organ transplant services will have on the Maryland system. Efficiency of the hospital can be determined by using the Health Services Cost Review Commission’s most recent comparison of hospital efficiency (this is currently the new Interhospital Cost Comparison Methodology) to compare the hospitals in the review. If one of the hospitals in a comparative review performs extremely poorly on the HSCRC’s evaluation, the Commission should clearly consider this poor performance in its review. The effect that a new organ transplant service may have on the Maryland system as a whole can be further determined by comparing the total additional revenue that the new program will generate at minimum State Health Plan volumes. Any applicant that offers to accept less revenue than it would normally be entitled to from this new program could be given a preference from the Commission in its review.

The State Health Plan chapter covering cardiac surgery and therapeutic catheterization services (COMAR 10.24.17) includes under its cost effectiveness policy, that in the case of a comparative review of applications, the Commission will give preference to the applicant that offers the best balance between program effectiveness and costs to the health care system as a whole.

In general, the organizations do support the use of preference standards (see F.2, page 21). Currently, the State Health Plan on organ transplant services outlines only one preference standard, namely, giving preference to applicants with an established prevention or early

intervention program addressing the specific medical conditions leading ultimately to transplantation, with particular outreach to minority and indigent patients in the hospital's regional service area.

Establishing a cost efficiency standard will ensure that Maryland residents receive high-cost organ transplant services in an effective and efficient manner.

◆ **Staff Recommendation:**

Staff recommends the adoption of a cost effectiveness preference standard (Option 2).

### ***E. Access to Care***

No options were provided for 'Access to Care'; however, UMMC wrote in support of the current policy regarding access to care.

Policies governing access to organ transplant services in the State Health Plan focus on both geographic and financial access to care. From the standpoint of geographic access, the plan uses one-way driving time to measure access to existing organ transplant programs. Despite the clustering of transplant centers and their programs in Baltimore City and the Washington, D.C. metropolitan area, most Maryland residents are within a three hour one-way driving time to at least one of each type of transplant program.

Financial access to care is encouraged by requiring each hospital to develop a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services regardless of an individual's ability to pay.

### ***F. Other Policies***

#### **1. Exemptions from Policies**

*Option 1: Waiver for Research Projects for Limited Time with Conditions*

*Option 2: Requirement for All Participating Institutions to have Institutional Review Board or Equivalent*

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of a combination of Option 1 and Option 2. The first criterion of Option 1 should be revised to require institutions without an IRB to have an external review of the protocol before a waiver is granted.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 2, requiring all participating institutions to have an IRB or externally validated equivalent process before waivers are granted.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** –endorsed a combination of Option 1 and Option 2. Conditions 2 and 3 as outlined in Option 1 should be met in order to be eligible for exemption; however, the requirement outlined in Option 2 of an external review of protocols should apply to institutions that do not have an IRB.

◆ **Changes Suggested by Comments:**

All three organizations recommended a modification to the current policy; that is, the authority to waive certain policies in the State Health Plan with specific conditions should be augmented with the inclusion of the requirement of an external review of protocols for institutions that do not have an Institutional Review Board (IRB).

◆ **Staff Analysis:**

Under section 46.103 of the Code of Federal Regulations (CFR), the Office of Human Research Protections (OHRP) requires each institution engaged in research involving the use of human subjects to appoint members to a formal review board (IRB) whose function is to review all projects generated by members of that institution and assure that each follows the basic guidelines set forth by 45 CFR 46. Certain guidelines have been established by the OHRP; however, authority has been given to the States and individual institutions to establish stricter guidelines as deemed appropriate. OHRP has the power to refuse Federal funding to any institution that does not have a functioning IRB.

In the situation of cooperative research projects (i.e., projects that involve more than one institution), each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the Federal Policy for the Protection of Human Subjects (§ 46.114). With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

IRBs are important, as their chief function is to represent the best interests of the patients or healthy volunteers who serve as research subjects. IRBs achieve this goal, in part, by:

- Reviewing research to ensure that potential benefits outweigh risks to participants;
- Ensuring that the rights and welfare of subjects are safeguarded, including the fairness of selection procedures and proper management during the conduct of the study; and
- Ensuring that all appropriate steps needed for true Informed Consent are planned and carried out.

The Commission currently has the authority to waive policies in the State Health Plan for a limited time with specific conditions related to research projects to meet a national need, and for which local conditions offer special advantage.

The current Plan states that, in order to be eligible for this exemption, several conditions must be met:

- 1) Prior to initiation of the project, the research proposal must be reviewed by each participating facility's Institutional Review Board (IRB), or equivalent institutional body;

or if the institution does not have an IRB, the proposal shall have written documentation from that institution on its institutional readiness to support the patient care protocol.

- 2) The research proposal must receive a majority of its funding from a federal agency, other public agency, or private non-profit foundation that has authority over research on human subjects.
- 3) The funding agency or foundation has no financial affiliation with entities that stand to gain economically from the conduct or outcome of the trial.

Recent issues in human research have raised the importance of assuring patient protection and the crucial need to ensure adequate review of all research protocols. In light of these recent events, staff will support the requirements of Federal regulations and recommend that all institutions have a functioning IRB before a waiver is provided. In the situation of an institution participating in a cooperative project, the institution may rely upon the review of another qualified IRB.

◆ **Staff Recommendation:**

Staff recommends the adoption of Option 1, with the modification of requiring all institutions to have a functioning IRB, or in the situation of a cooperative research project an institution may rely on another institution's qualified IRB.

## **2. Preference Standards in Comparative Reviews**

<i>Option 1: Inclusion of Preference Standards</i> <i>Option 2: Elimination of Preference Standards</i>
--

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 1.

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1.

◆ **Changes Suggested by Comments:**

The three organizations submitting public comments all supported Option 1, maintaining preference standards as a provision in comparative CON reviews.

◆ **Staff Analysis:**

Preference standards encourage prospective applicants to address important health policy issues, which will be of benefit when applying for a CON in a highly competitive, comparative review situation. Currently, only one preference standard is included in the State Health Plan, namely, preference is given to applicants with an established prevention or early treatment program addressing the specific medical conditions leading ultimately to transplantation, with particular outreach to minority and indigent patients in the hospital's regional service area.

Option 1 also proposes the concept of introducing other preference standards. As discussed earlier in D.1 (page 18), introducing a cost efficiency preference standard would further reinforce the importance of balancing program effectiveness and health care costs.

◆ **Staff Recommendation:**

Staff recommends maintaining the current policy in regard to the use of preference standards in comparative CON reviews. In addition, staff recommends introducing a cost effectiveness preference standard (see D.1).

### **3. Merged Hospital Systems**

*Option 1: CON Required to Relocate Any Part of an Existing  
Organ Transplant Program to Another Hospital Within a  
Merged Hospital System*  
*Option 2: Relocation without CON*

◆ **Summary of Public Comments:**

**Ronald R. Peterson, President of JHHS** – wrote in support of Option 2. Merged hospital systems should be permitted to reconfigure transplant services without the requirement for a full CON review. JHHS noted that “hospital consolidation and merger projects exempt from CON review must still meet three review criteria: (i) consistent with the State Health Plan; (ii) will result in more efficient and effective delivery of health care services; and (iii) in the public interest.”

**John L. Green, Executive Vice President of Medstar Health** – wrote in support of Option 1.

**Stephen C. Schimpff, Chief Executive Officer of UMMC** – wrote in support of Option 1.

◆ **Changes Suggested by Comments:**

Two organizations wrote in support of maintaining the current policy, requiring merged hospital systems to undergo a CON review to relocate any part of an existing organ transplant program. JHHS suggested that Option 2 provides flexibility to create efficient systems and reduce administrative burden associated with CON reviews, but still gives the Commission oversight to ensure compliance with a coordinated statewide plan.

◆ **Staff Analysis:**

Although hospital consolidation and merger projects exempt from CON review must still meet three review criteria, the staff believes that those criteria do not guard against the complex issues involved in this specialized health care service.

Exemption from CON (i.e., meeting the three review criteria) does not ensure that the proposed new location for the program is needed or that it meets other standards related to financial solvency, geographic accessibility, and cost-effectiveness, as a CON review does.

Organ transplantation is known to be a high-cost, low-volume service, where a volume-quality relationship has been established. There is concern that if a CON review is not required when a merged hospital system relocates any part of an existing organ transplant program to another hospital within its system, it may result in proliferation of services and increased costs.

Staff continues to support Policy 6 in COMAR 10.24.15, where fewer organ transplant services operating at higher volumes are preferable to more programs at threshold or minimum volumes.

◆ **Staff Recommendation:**

Staff recommends maintaining the current policy that a CON is required to relocate any part of an existing organ transplant program to another hospital within its merged hospital system.



(Blank)

**APPENDIX A:**  
**Summary of Preferred Options from Public Comments and**  
**Staff Recommendation for Each Issue**

(Blank)

**Appendix A: Summary of Preferred Options from Public Comments and Staff  
Recommendation for Each Issue**

Issue	Description	Preferred Option			Staff Recommendation
		JHHS	MedStar	UMMC	
A	Categories of transplant programs	1	1	1	1
B1	Planning regions	2	1	Modified 2	1
B2	Migration patterns	2	2	2	1
B3	Use rate assumptions	4	Either 2 or 3	2 & 4	2
B4	Planning horizon	2	1	2	1
B5	Determination of need for a new program	1	1	1	1
C1	Minimum and threshold volume standards	1	1	1	1
D1	Cost efficiency standard	1	2	1	2
F1	Exemption policy	Combine 1 & 2	2	Combine 1 & 2	Combine 1 & 2
F2	Preference standards	1	1	1	1, with addition of cost efficiency
F3	Merged hospital systems	2	1	1	1

(Blank)

**APPENDIX B:**  
**Projected Use Rates, Cases and Migration Patterns**

(Blank)

## Appendix B: Projected Utilization for Organ Transplant Programs by Regional Service Area

The following table presents projected use rates, cases and migration patterns for organ transplant programs by regional service area. These projections were calculated using the methodologies in the draft COMAR 10.24.15 State Health Plan: Specialized Health Care Services – Organ Transplant Services.

Transplant Type	Projection Rates For 2003	Residence of Patient	
		Maryland Region	Washington Region
Kidney	Projected Use Rate	20.23	6.46
	Projected Cases	691	272
	In-Migration	38.7%	19.4%
	Out-Migration	7.5%	15.4%
Pancreas	Projected Use Rate	1.32	0.31
	Projected Cases	45	13
	In-Migration	60.2%	33.3%
	Out-Migration	6.8%	45.7%
Liver	Projected Use Rate	1.90	1.66
	Projected Cases	65	70
	In-Migration	42.0%	34.4%
	Out-Migration	25.5%	48.2%
Heart	Projected Use Rate	0.39	0.60
	Projected Cases	13	25
	In-Migration	38.4%	27.7%
	Out-Migration	31.8%	25.4%
Lung	Projected Use Rate	0.37	1.12
	Projected Cases	13	47
	In-Migration	56.5%	40.5%
	Out-Migration	19.6%	51.9%
Autologous*	Projected Use Rate	5.89	2.29
	Projected Cases	201	97
	In-Migration	36.0%	32.1%
	Out-Migration	7.6%	21.7%
Allogeneic*	Projected Use Rate	3.95	0.89
	Projected Cases	135	37
	In-Migration	58.9%	31.7%
	Out-Migration	9.6%	46.7%

\*Base year 1999; projections for 2002.



(Blank)

## **APPENDIX C: Written Comments Received**

1. Johns Hopkins Health System – Ronald R. Peterson, President
2. MedStar Health – John L. Green, Executive Vice President, Corporate Services
3. University of Maryland Medical Center – Stephen C. Sch mipff, Chief Executive Officer

(Blank)